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10/531,546	10/21/2005	William R. Freeman	00015-017001/SD2001-200-1	3894

26138 7590 02/05/2009  
Joseph R. Baker, APC  
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4660 La Jolla Village Drive, Suite 750  
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EXAMINER
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HUANG, GIGI GEORGIANA

ART UNIT	PAPER NUMBER
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1612

MAIL DATE	DELIVERY MODE
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02/05/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/531,546	<b>Applicant(s)</b> FREEMAN, WILLIAM R.	
	<b>Examiner</b> GIGI HUANG	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-37 and 40-42 is/are pending in the application.
- 4a) Of the above claim(s) 19-23,25-37 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18,24,41 and 42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

**Request for Continued Examination**

***Status of Application***

1. The response filed November 3, 2008 has been received, entered and carefully considered. The response affects the instant application accordingly:
  - a. Claim 1 has been amended.
2. Claims 1-37 and 40-42 are pending in the case.
3. Claims 1-18, 24, and 41-42 are present for examination.
4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.
5. All grounds not addressed in the action are withdrawn or moot.
6. New grounds of rejection are set forth in the current office action.

***New Grounds of Rejection***

7. Due to the amendment of the claims the new grounds of rejection are applied:

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-3, 6-11, 13-18, 24, 41-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The term "photosensitizer" is not defined and it does not address what materials, components, or compounds currently or yet to be made would fulfill the description.

The term "photosensitizer" is not adequately described as it is defined by a functional characteristic where it is defined by what it *does* and not what it *is*. Second, it does not describe adequately the degree activity to ascertain what compounds would fulfill the description as it includes compounds that have not yet made and the recitation of absorption spectrums are properties inherent to the component but as it is a recitation of what it can do and not what it is, does not adequately describe the "photosensitizer". As a result, the fact pattern indicates that the artisan was not in possession of the claimed method of use.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-11, 13-18, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recited the dose to be "greater than about 50j/cm<sup>2</sup>". The term "greater than about" is a relative term that renders the claims indefinite. The term "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the

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invention. The term is unclear as to what the endpoints of the ranges/limitations are for the claim.

See *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991), where the court held that claims reciting “at least about” were invalid for indefiniteness where there was close prior art and there was nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity is covered by the term “about.” (See MPEP 2173.05 [R-5] “Relative Terminology”.) This ruling would apply equally to “greater than about”.

For purposes of prosecution, and amount applies.

12. Claims 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are to identification off the feeder with image analysis.

- a. Claim 11 is unclear as it is broader than the independent claim 1 which recites identification of the feeder with a high speed scanning laser ophthalmoscope. It does not allow one of skill in the art to ascertain the metes and bounds of the invention. For purposes of prosecution, the claim is viewed as to SLO.
- b. Claim 12 is unclear as it is to a different method of image analysis than the method recited in independent claim 1 which recites identification of the feeder with a high speed scanning laser ophthalmoscope. It does not allow one of skill in the art to ascertain the metes and bounds of the invention as it is contrary to the

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methods presented in the independent claim. As a result, the claim cannot be further treated on its merits.

c. Claim 13 is unclear as it is dependent from claim 11 which as addressed above is indefinite and claim 13 is reciting the same method step as the one presented in the independent claim 1 (high speed scanning laser ophthalmoscope). It is unclear what the intended limitation is as it currently fails to further limit the independent claim and depends from a claim that is broader than the independent claim from which it depends. It does not allow one of skill in the art to ascertain the metes and bounds of the invention. For purposes of prosecution, the claim is viewed as to SLO.

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 1-8, 10-11, 13-17, 24, 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (U.S. Pat. No. 5798349) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovascularization in the Era of Photodynamic Therapy With Verteporfin) and Roach (EyeNet Magazine March 2001).

Levy et al. teaches a method of photodynamic therapy for unwanted neovasculture in the eye specifically in Age-related macular degeneration. Fundus photography, histological examination, and fluorescein angiography were used to

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observe and identify the choroidal revascularization. A green porphyrin, BPD-MA (verteporfin), was combined with lipoproteins, and injected intravenously in a leg vein. The eyes were then irradiated with a laser at 692 nm to treat the areas of choroidal neovascularization. The fluence for the treatment sites in the examples were 50, 75, 100 or 150 joules/cm<sup>2</sup>. Subsequent angiography was used to show the closure of the vasculature (Abstract, Col.1, lines 18-48, 55-63, Col. 2, lines 13-32, 39-52, Col. 3, lines 32-40, 45-68, Col. 4, lines 1-64, Col. 6, lines 1-36, Col. 8, lines 26-45, Examples 1-2, Col. 9-10, Example 3 and 4, Col. 11 Table 5). Levy also teaches that laser photocoagulation treatment is also available for the condition and depending on the side effects, scarring, and level of prognosis; strategies such as photodynamic therapy are desirable since there is greater selective closure of the blood vessels.

Levy et al. does not expressly teach the method for treating an aberrant choroidal neovascularization in an extrafoveal area of the eye or use of high speed scanning laser ophthalmoscope.

Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovascularization in the Era of Photodynamic Therapy With Verteporfin) teaches that photodynamic therapy (PDT) with verteporfin is well-known for treating patients with subfoveal choroidal neovascularization (CNV) and should be considered for the therapy of CNV that is not subfoveal in certain situations such as juxtafoveal and extrafoveal CNV. Jampol teaches that there are some situations where the use of PDT with verteporfin would be particularly desirable as thermal lasers produce an absolute scotoma verses PDT with verteporfin which could allow the survival of the retina over

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the CNV, and that successful PDT with verteporfin could allow for a better result.

Jampol teaches that the combination of therapies could be more beneficial than either alone. Additionally, it may be possible to treat a juxtafoveal or extrafoveal membrane with PDT first and see the results. If the lesion continues to grow, then thermal lasers (e.g. laser photocoagulation) could be considered as a next step if needed. The reverse is also contemplated, whereby treatment with the laser is not successful, PDT with verteporfin would be considered. Jampol also addressed that the PDT outcome for extrafoveal CNV lesions would be better than with subfoveal, and juxtafoveal area would be with an intermediate result (Pages 99-101).

Roach teaches that new and sophisticated imaging systems are improving the results of feeder vessel treatment in macular degeneration. Essentially, it is easier to treat a blood vessel you can see than one you cannot. Roach teaches that real-time digital imaging systems for high-speed indocyanine green angiography (HSICG) coupled with a scanning laser ophthalmoscope can produce real time imaging where the indocyanine green dye used can be seen moving through the choroidal vessels.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize photodynamic therapy for CNV in the extrafoveal area of the eye, as suggested by Jampol et al., to utilize the scanning laser ophthalmoscope with high-speed indocyanine green angiography, as suggested by Roach, and produce the instant invention. It would have been obvious to one of skill in the art to utilize the PDT in the extrafoveal region as CNV lesions in the eye would be expected to have better favorable outcomes even compared to the classic subfoveal

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and could allow the survival of the retina over the CNV which is desirable. It also would have been obvious to one of skill in the art at the time the claimed invention was made to utilize the scanning laser ophthalmoscope with high-speed indocyanine green angiography, as the imaging technique would also be invaluable in photodynamic therapy to allow the physician to produce real time imaging where the dye used can be seen moving through the choroidal vessels and identify the aberrant vessels and improve the accuracy and images available to the practitioner to diagnosis and perform the therapy effectively.

One of ordinary skill in the art would have been motivated to do this because as taught by Jampol and Roach, there are some situations where the use of PDT with verteporfin would be particularly desirable as thermal lasers produce an absolute scotoma verses PDT with verteporfin which could allow the survival of the retina over the CNV, and that successful PDT with verteporfin could allow for a better result, such as extrafoveal and juxtafoveal CNV. Additionally, as the scanning laser ophthalmoscope coupled with the high-speed indocyanine green angiography (HSICG) operates in real time, it is possible to immediately treat an area as it is identified. The system increases the number of vessels you can see, thereby allowing the practitioner to increase number of vessels to be treated which results in increasingly effective and accurate treatment which is desirable.

15. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (U.S. Pat. No. 5798349) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovascularization in the Era of Photodynamic Therapy With

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Verteporfin) and Roach (EyeNet Magazine March 2001) as applied to claims 1-8, 10-11, 13-17, 24, 41-42 above, and in view of Levy et al. (U.S. Pat. No. 4920143).

The teachings of Levy et al. in view of Jampol et al. and Roach are discussed above.

Levy et al. in view of Jampol et al. and Roach does not expressly teach the topical application of the photosensitizer.

Levy et al. (U.S. Pat. No. 4920143), which is fully incorporated by reference in Levy et al. (U.S. Pat. No. 5798349), teaches that the photosensitizing compounds can be administered for systemic or topical use in formulations well known in the art (Col. 10, lines 65-68, Col. 11, lines 1-33).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to try topical administration, as suggested by Levy, and produce the instant invention. It would have been obvious to try topical administration as it would be another method of administration if adequate intravenous lines would not be available such as collapsed veins.

One of ordinary skill in the art would have been motivated to do this because topical administration does not require additional equipment such as IV drips and saline flushes, simplifying the procedure and cost to the practitioner.

16. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (U.S. Pat. No. 5798349) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovascularization in the Era of Photodynamic Therapy With

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Verteporfin) and Roach (EyeNet Magazine March 2001) as applied to claims 1-8, 10-11, 13-17, 24, 41-42 above, and in view of LumaCare (Press release - <http://lumacare.com/EMEA/pr3.html>).

The teachings of Levy et al. in view of Jampol et al. and Roach are discussed above. Levy also teaches the use of coherent light (lasers) in photodynamic therapy.

Levy et al. in view of Jampol et al. and Roach does not expressly teach the use of non-coherent light.

LumaCare teaches the use, availability, and benefit of the LumaCare LC-122 a non-coherent light source for affordable photodynamic therapy activation. The product is compact, lightweight, portable, safer, easier to use, and more affordable to implement than lasers. It can generate light frequencies from 400-800nm for a wide range of photodynamic therapy (PDT) and requires minimal maintenance.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use non-coherent light, as suggested by LumaCare, and produce the instant invention. As taught by LumaCare, traditional light sources for PDT are lasers that are expensive and most are only able to produce a narrow range of light frequencies. The LumaCare is more affordable with greater range of frequencies for various PDT treatments, portable, requires minimal training of staff, and as a result, very cost effective.

One of ordinary skill in the art would have been motivated to do this because not only is LumaCare affordable, it can be used in multiple treatment rooms increasing the number of patients that can be treated. This decreases the overhead, increases

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efficiency, and increases productivity of the practitioner thereby providing more income, which is desirable.

17. Claims 1-8, 10-11, 13-17, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan (Jacksonville Medicine) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovascularization in the Era of Photodynamic Therapy With Verteporfin) and Roach (EyeNet Magazine March 2001).

Sullivan teaches the method of treating choroidal neovascularization caused by age-related macular degeneration. The method utilized fluorescein angiograms to determine the presence, location, and extent of the choroidal neovascularization by injection of a dye into a vein and multiple photographs of the retina. Treatment followed with the use of photodynamic therapy utilizing verteporfin coupled with low-density lipoprotein and injected intravenously. A non-thermal laser light was then used to activate the verteporfin at the area of neovascularization. The wavelength used was 689 nm, corresponding to the absorption peak of the verteporfin dye. The result was thrombosis and occlusion of the abnormal vessel (Pages 396-398).

Sullivan et al. does not expressly teach the method for treating an aberrant choroidal neovasculature in an extrafoveal area of the eye or the use of a high speed scanning laser ophthalmoscope.

Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovascularization in the Era of Photodynamic Therapy With Verteporfin) teaches that photodynamic therapy (PDT) with verteporfin is well-known for treating patient with subfoveal choroidal neovascularization (CNV) and should be considered for the therapy

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of CNV that is not subfoveal in certain situation such as juxtafoveal and extrafoveal CNV. Jampol teaches that there are some situations where the use of PDT with verteporfin would be particularly desirable as thermal laser produce an absolute scotoma verses PDT with verteporfin which could allow the survival of the retina over the CNV, and that successful PDT with verteporfin could allow for a better result. Jampol teaches that the combination of therapies could be more beneficial than either alone. Additionally, it may be possible to treat a juxtafoveal or extrafoveal membrane with PCT first and see the results. If the lesion continues to grow, then thermal lasers could be considered as a next step if needed. The reverse is also contemplated, whereby treatment with the laser is not successful, then PDT with verteporfin would be considered. Jampol also addressed that the PDT outcome for extrafoveal CNV lesions would be better than with subfoveal, and juxtafoveal area would be with an intermediate result (Pages 99-101).

Roach teaches that new and sophisticated imaging systems are improving the results of feeder vessel treatment in macular degeneration. Essentially, it is easier to treat a blood vessel you can see than one you cannot. Roach teaches that real-time digital imaging systems for high-speed indocyanine green angiography (HSICG) coupled with a scanning laser ophthalmoscope can produce real time imaging where the indocyanine green dye used can be seen moving through the choroidal vessels.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize photodynamic therapy for CNV in the extrafoveal area of the eye, as suggested by Jampol et al., to utilize the scanning laser

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ophthalmoscope with high-speed indocyanine green angiography, as suggested by Roach, and produce the instant invention. It would have been obvious to one of skill in the art to utilize the PDT in the extrafoveal region as CNV lesions in the eye would be expected to have better favorable outcomes even compared to the classic subfoveal and could allow the survival of the retina over the CNV which is desirable. It also would have been obvious to one of skill in the art at the time the claimed invention was made to utilize the scanning laser ophthalmoscope with high-speed indocyanine green angiography, as the imaging technique would also be invaluable in photodynamic therapy to allow the physician to produce real time imaging where the dye used can be seen moving through the choroidal vessels and identify the aberrant vessels and improve the accuracy and images available to the practitioner to diagnosis and perform the therapy effectively.

One of ordinary skill in the art would have been motivated to do this because as taught by Jampol and Roach, there are some situations where the use of PDT with verteporfin would be particularly desirable as thermal lasers produce an absolute scotoma verses PDT with verteporfin which could allow the survival of the retina over the CNV, and that successful PDT with verteporfin could allow for a better result, such as extrafoveal and juxtafoveal CNV. Additionally, as the scanning laser ophthalmoscope coupled with the high-speed indocyanine green angiography (HSICG) operates in real time, it is possible to immediately treat an area as it is identified. The system increases the number of vessels you can see, thereby allowing the practitioner to increase number

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of vessels to be treated which results in increasingly effective and accurate treatment which is desirable.

18. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan (Jacksonville Medicine) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovascularization in the Era of Photodynamic Therapy With Verteporfin) and Roach (EyeNet Magazine March 2001) as applied for claims 1-8, 10-11, 13-17, 24, and further in view of Levy et al. (U.S. Pat. No. 4920143).

The teachings of Sullivan, Jampol et al., and Roach are discussed above.

Sullivan in view of Jampol et al. and Roach does not expressly teach the topical application of the photosensitizer.

Levy et al. (U.S. Pat. No. 4920143) teaches that the photosensitizing compounds can be administered in formulations well known in the art for systemic or topical use (Col. 10, lines 65-68, Col. 11, lines 1-33).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to try topical administration, as suggested by Levy, and produce the instant invention. It would have obvious to try topical administration as it would be another method of administration if adequate intravenous lines would not be available such as collapsed veins.

One of ordinary skill in the art would have been motivated to do this because topical administration does not require additional equipment such as IV drips and saline flushes, simplifying the procedure and cost to the practitioner.

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19. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan (Jacksonville Medicine) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovascularization in the Era of Photodynamic Therapy With Verteporfin) and Roach (EyeNet Magazine March 2001) as applied for claims 1-8, 10-11, 13-17, 24 above, and in view of LumaCare (<http://lumacare.com/EMEA/pr3.html>).

The teachings of Sullivan, Jampol et al., and Roach are discussed above.

Sullivan, Jampol et al., and Roach teach the use of coherent light (lasers) in photodynamic therapy.

Sullivan, in view of Jampol et al. and Roach does not expressly teach the use of non-coherent light.

LumaCare teaches the use, availability, and benefit of the LumaCare LC-122 a non-coherent light source for affordable photodynamic therapy activation. The product is compact, lightweight, portable, safer, easier to use, and more affordable to implement than lasers. It can generate light frequencies from 400-800nm for a wide range of photodynamic therapy (PDT) and requires minimal maintenance.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use non-coherent light, as suggested by LumaCare, and produce the instant invention. As taught by LumaCare, traditional light sources for PDT are lasers that are expensive and most are only able to produce a narrow range of light frequencies. The LumaCare is more affordable with greater range of frequencies for various PDT treatments, portable, requires minimal training of staff, and as a result, very cost effective.

One of ordinary skill in the art would have been motivated to do this because not only is LumaCare affordable, it can be used in multiple treatment rooms increasing the number of patients that can be treated. This decreases the overhead, increases efficiency, and increases productivity of the practitioner thereby providing more income, which is desirable.

20. Claims 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan (Jacksonville Medicine) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovascularization in the Era of Photodynamic Therapy With Verteporfin) and Roach (EyeNet Magazine March 2001) as applied for claims 1-8, 10-11, 13-17, 24, and further in view of Miller et al. (U.S. Pat. No. 5707986).

The teachings of Levy et al. in view of Jampol et al. and Roach are discussed above.

Levy et al. in view of Jampol et al. and Roach does not expressly teach the fluence of the photoactivating light.

Miller et al. teaches the use of a green porphyrin, BPD-MA (verteporfin) for treating the choroidal neovascularization and other conditions. The BPD-MA was combined with lipoproteins, and injected intravenously in a leg vein. The eyes were then irradiated with a laser at 692 nm to treat the areas of choroidal neovascularization. Miller teaches that the porphyrin is used within the range of about 0.1 to about 20mg/kg, preferably from about 0.15-2.0mg/kg. Specifically, when the green porphyrin dose is reduced from about 2 to about 1mg/kg, there is a corresponding increase in the fluence required to close the choroidal neovascular tissue, such as from about 50 J/cm<sup>2</sup> to

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about  $100\text{J}/\text{cm}^2$ . The green porphyrin has a maximum absorbance of about 550 to 695nm which is the wavelength used to radiate the porphyrin. The fluence for treatment can vary depending the tissue, depth, and amount of fluid/blood, but preferably varies from about 50-200  $\text{J}/\text{cm}^2$ . The examples utilized for the treatment sites, verteporfin irradiated with a wavelength of 692, and fluences of 50, 100, and 150 joules/ $\text{cm}^2$  were utilized to effectively close the choroidal neovascularization. Subsequent angiography was used to show the closure of the vasculature (Abstract, Col.3, lines 1-68, Col. 4, lines 1-33, Col. 5, lines 29-55, Col. 7, lines 17-65, Col. 8, lines 55-68, Col.10-12, Example 3 and 4).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize the fluence levels for photodynamic therapy as suggested by Jampol et al., with as suggested by Miller, and produce the instant invention. It would have been obvious to one of skill in the art to use the taught fluence amounts of photoactive light for irradiation of verteporfin effective to close the choroidal neovascularization. It is obvious to use the amounts and ranges taught by Miller for the fluence as the dye (verteporfin) utilized is the same, with photoactive light in the same wavelength ranges taught, and for the same purpose for the same conditions to yield the same result, the closure of the abnormal vasculature.

One of ordinary skill in the art would have been motivated to use known amounts and technique for the same treatment with the taught amounts and ranges known to be effective for closure of the choroidal neovascularization.

***Response to Arguments***

21. Applicant's arguments are considered but in view of the amendments to the claims, the arguments are moot and the new rejections are applied as addressed above.

***Conclusion***

22. Claims 1-18, 24, and 41-42 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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